Effect of administration of single dose Histidine-Tryptophane-Ketoglutarate (HTK) cardioplegia solution on serum sodium concentration, osmolarity and acid-base balance.

Published: 10-04-2017
Last updated: 14-04-2024

To analyse serum sodium concentration, serum osmolarity and arterial bloodgas at different times before and after administration of HTK solution, to get more insight of the impact of this solution on these biochemical parameters and to improve our...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON43165

Source
ToetsingOnline

Brief title
Effect of HTK on serum sodium concentration, osmolarity.

Condition

- Other condition

Synonym
hyponatriemia, low sodium concentration

Health condition

electrolytstoornissen en stoornissen in osmolariteit en het zuur-base evenwicht

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: standaard behandeling;geen extra kosten

Intervention

Keyword: Cardioplegia, Histidine-Tryptophane-Ketoglucorate, osmolarity, sodium concentration

Outcome measures

Primary outcome

Serum sodium concentration

Osmolarity

Acid-base balance

Secondary outcome

Acid-base balance

Study description

Background summary

The introduction of cardiopulmonary bypass (CPB) in the 1950*s has allowed induction of cardiac arrest by administering cardioplegia solution.[1]
Cardioplegia solutions improve the tolerance to ischaemia and reperfusion by preserving myocardial energy reserves, preventing osmotic and electrolyte imbalances and buffering acidosis.
Histidine-tryptophane-ketoglucorate (HTK) and St. Thomas* cardioplegia solution are used by default for most cardiothoracic procedures at the Catharina Hospital Eindhoven. The chosen cardioplegia solution depends on the time-length of the specific cardiothoracic procedure. Patients undergoing cardiothoracic procedures in which the estimated aortic clamping time exceeds 120 minutes will receive single dose HTK cardioplegia solution. These procedures include triple valve surgery, double valve + coronary artery bypass grafting and aortic arch surgery. Patients undergoing coronary artery bypass grafting or single valve

surgery alone will receive St. Thomas* cardioplegia solution as the aortic clamping time is generally less than 120 minutes.

Cardioplegia with histidine-tryptophane-ketoglucorate (HTK) for cardiac arrest has been widely used clinically and reported in more than 700.000 cases of open cardiac surgery.2 It is simple to use, administered as one single dose, and it is claimed to give sufficient myocardial protection for more than 2 hours of cardiac arrest.3 Therefore, single dose cardioplegia administration is an attractive option in more complex cardiac procedures as re-administration of cardioplegia can disturb the technical flow of the operation. However, HTK cardioplegia solution is hyponatremic (15 mmol/l) compared to serum sodium concentration (140 mmol/l) and could lead to severe hyponatremia if administered in high volumes. Rapid development of hyponatremia can lead to cerebral swelling which can ultimately end in brain herniation and even death.4 Treatment of acute hyponatremia however is not straightforward in this case, as HTK cardioplegia solution is slightly hypertonic (310 mosmol/kg). Administration of this solution might therefore lead to isotonic hyponatremia, in which correction of serum sodium levels would be harmful, as a hyperosmolar state with cerebral shrinking as a consequence could be induced.
Besides one study from Lindner et al in 2012, measurement of serum sodium concentration has never been correlated to serum osmolarity. In the aforementioned study serum osmolarity was measured in only 7 out of 25 patients. In this study isotonicity during acute hyponatriemia after cardioplegia with HTK solution was shown. However, a larger sample size would be reasonable to confirm that administration of HTK cardioplegia solution will lead to isotonic hyponatremia and does not need any correction indeed.
In this observational study we want to get more insight in the biochemical disturbances (sodiumconcentration, acid-base balance and osmolarity) that the cardiosurgical patient is exposed to in our own institution during every day practice. Serum osmolarity is not a standard laboratory measurement in the perioperative setting and data from earlies studies are sparse. We are striving for improvement of our daily perioperative quality of care.

Study objective

To analyse serum sodium concentration, serum osmolarity and arterial bloodgas at different times before and after administration of HTK solution, to get more insight of the impact of this solution on these biochemical parameters and to improve our daily practice in management of hyponatremia after HTK cardioplegia administration.
In addition, to evaluate the above mentioned parameters in time after administration of St Thomas* cardioplegia solution. It*s not our intention to compare HTK and St Thomas* results one to one, but to get more insight in the consequences of our daily clinical practice.

Study design

Monocenter, prospective, observational study

Study burden and risks

Blood sampling will be done through an arterial line, which will be placed standardly at the start of anesthesia for a cardiosurgical procedure. Participation in this study therefore does not lead to additional risk. Multiple bloodsampling may lead to anaemia. The needed volumes are small however, and the numer of samples are limited. Most biochemical analyses can be done from the bloodsamples taken at the Intensive Care for routine postoperatieve laboratory testing. The maximum sampling volume will be 25 ml of blood per patient in total. The risk of any disadvantageous health effect for the patient is negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* patients undergoing non emergency cardiothoracic surgery where HTK solution or St Thomas' cardioplegia solution will be used for myocardial protection
* Older than 18 years

Exclusion criteria

* Emergency procedures
* Younger than 18 years
* Allergy to HTK or St Thomas' cardioplegie
* Serum sodium abnormalities before surgery

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-12-2017
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	10-04-2017

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL58335.100.16